

**Revelations from the  
Pandemic and Beyond**

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**ANNUAL MEETING  
2021**

## **Guest Speaker Session: Patient Safety Evaluation System Panel**

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# *ECRI and the ISMP PSO Annual Meeting*

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PSES Legal Panel  
November 3, 2021

# Provisos



- This is not legal advice.
- Please join the AQIPS Legal Counsel meetings ([Pbinzer@aqips.org](mailto:Pbinzer@aqips.org)).
- Any characters in any stories or examples are fictitious - any likeness to real people, events, or PSWP is purely coincidental.
- Please ask questions. This meeting is for you.

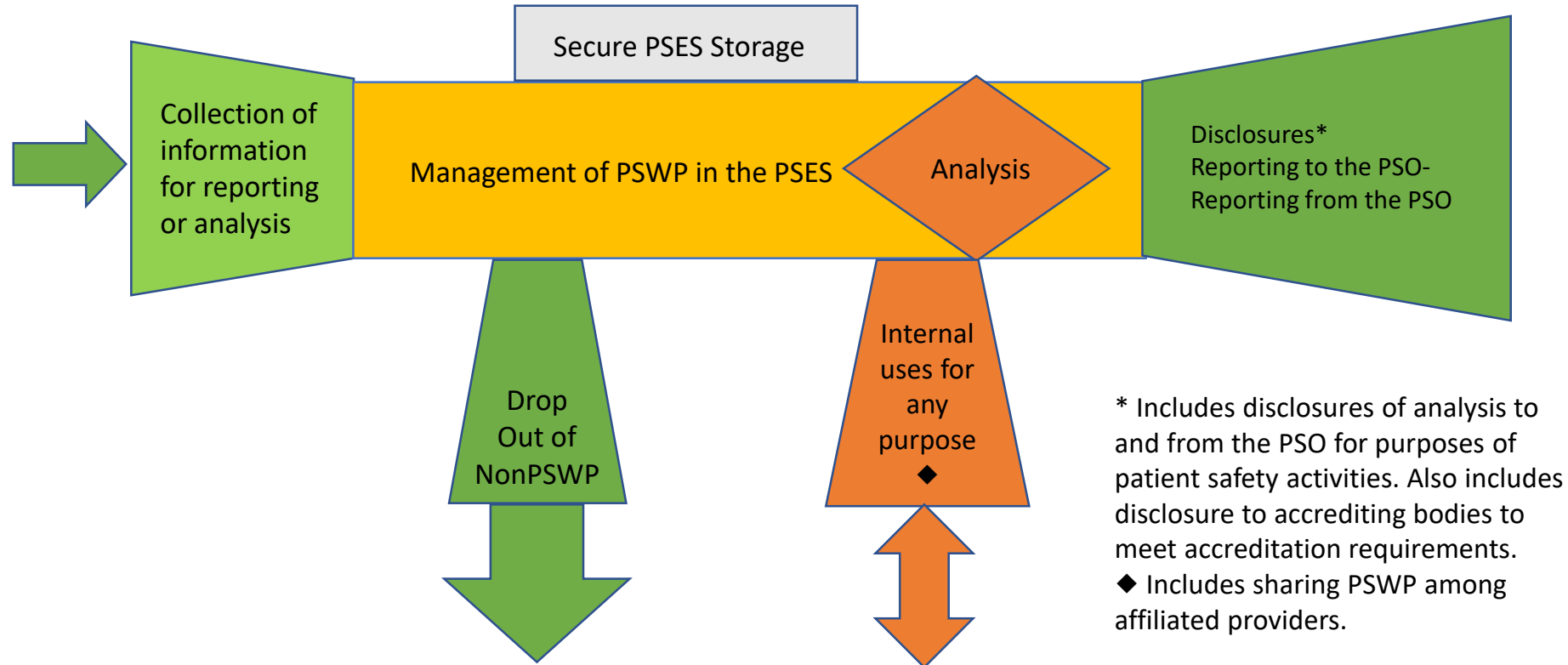
# Patient Safety Evaluation System (PSES)

PSES: Roadmap for the flow of information throughout your facility for conducting Patient Safety Activities. Including:

- Any effort to improve patient safety and the quality of patient care delivery
- The collection, management or analysis of *information* in the PSES
- For reporting information to a PSO
- For collecting information (i.e., feedback) from the PSO

The PSES does not itself require reporting to the PSO but provides a roadmap for the reporting, analysis, and PSO pathways.

# Provider PSES



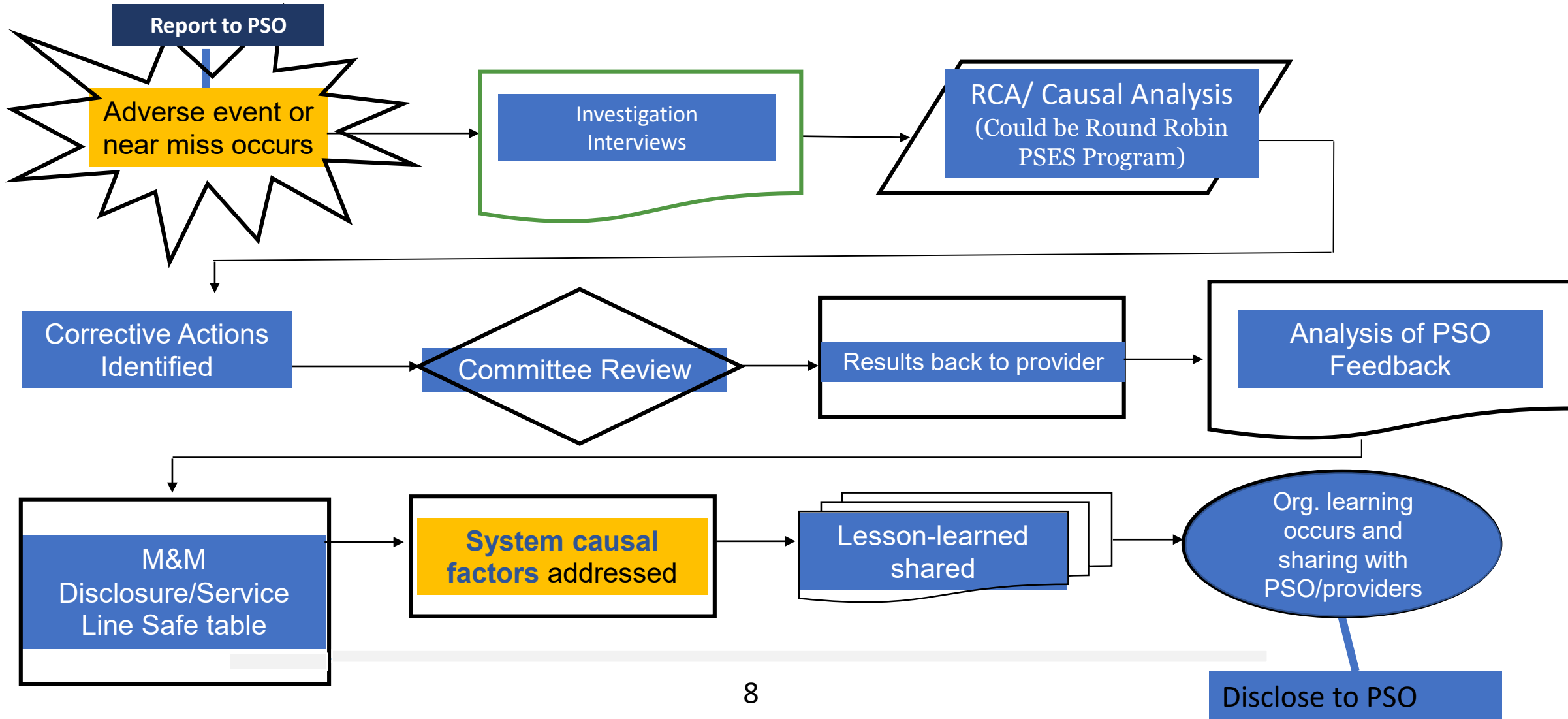
# Reporting Pathway

- Information collected and developed for reporting to a PSO which could improve quality, safety, and outcomes and is reported to the PSO is PSWP:
  - Patient Safety and Quality Related Events
  - Recordings
  - RCA Information (the RCA may or may not be PSWP depending upon whether it is developed in the PSES)
- Information developed by the PSO and reported to the Provider: Feed back (e.g., best practices, solutions, clinical protocols) is PSWP.

# Analysis and Deliberations Pathway

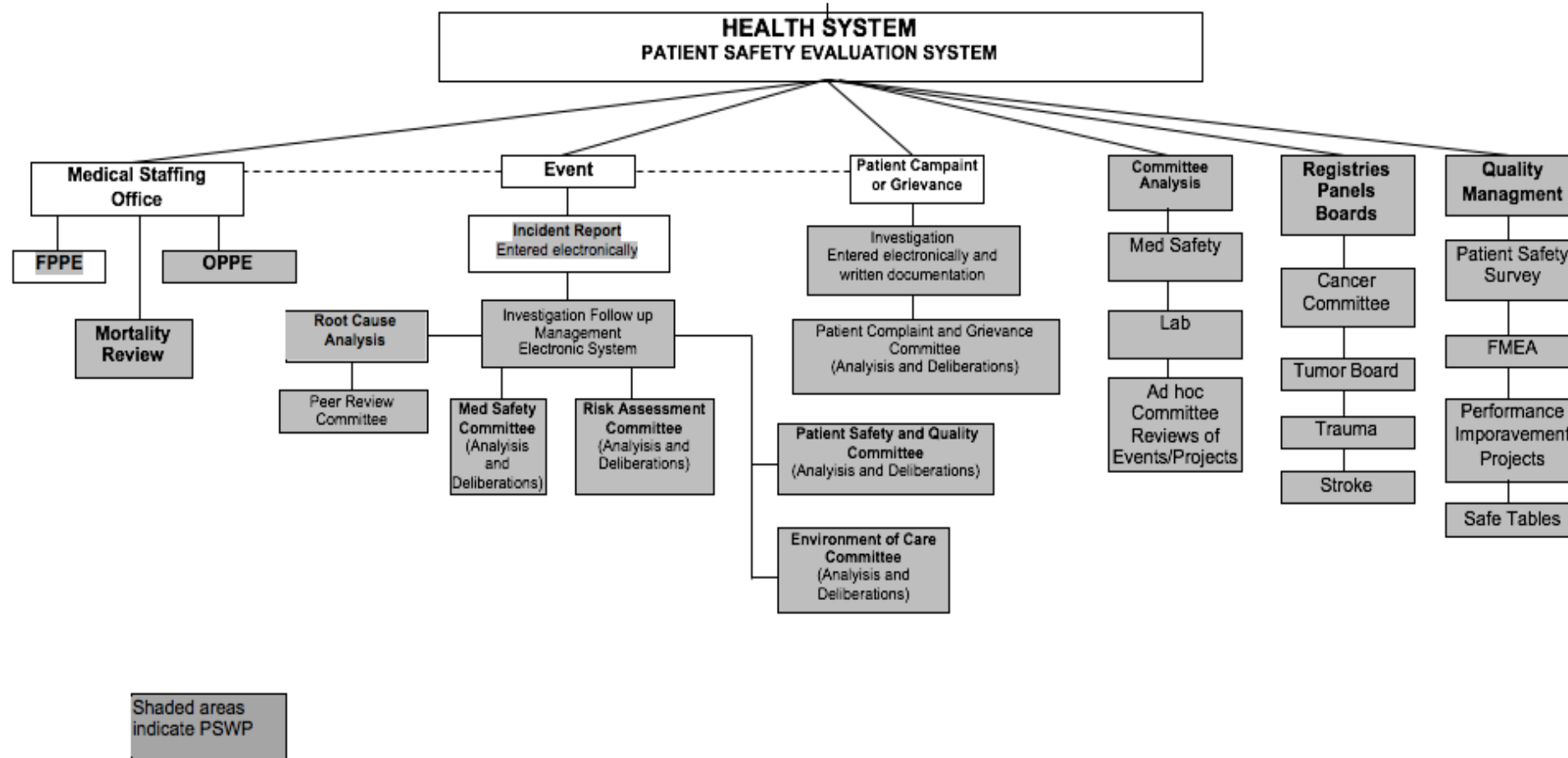
- Analysis and Deliberations that occur in the PSES are PSWP. Information that identifies analysis is PSWP.
- PSES policy and procedure best practices:
  - List all patient safety activities that occur in the PSES (where the PSES appears when the activity occurs):
    - RCA
    - Peer Review
  - List all committees, conferences, where PSWP is discussed and created:
    - Quality Committee
    - Provider safe tables
- List platforms and tools that can identify the analysis – emails, meta data, etc.

# PSES Analysis Pathway





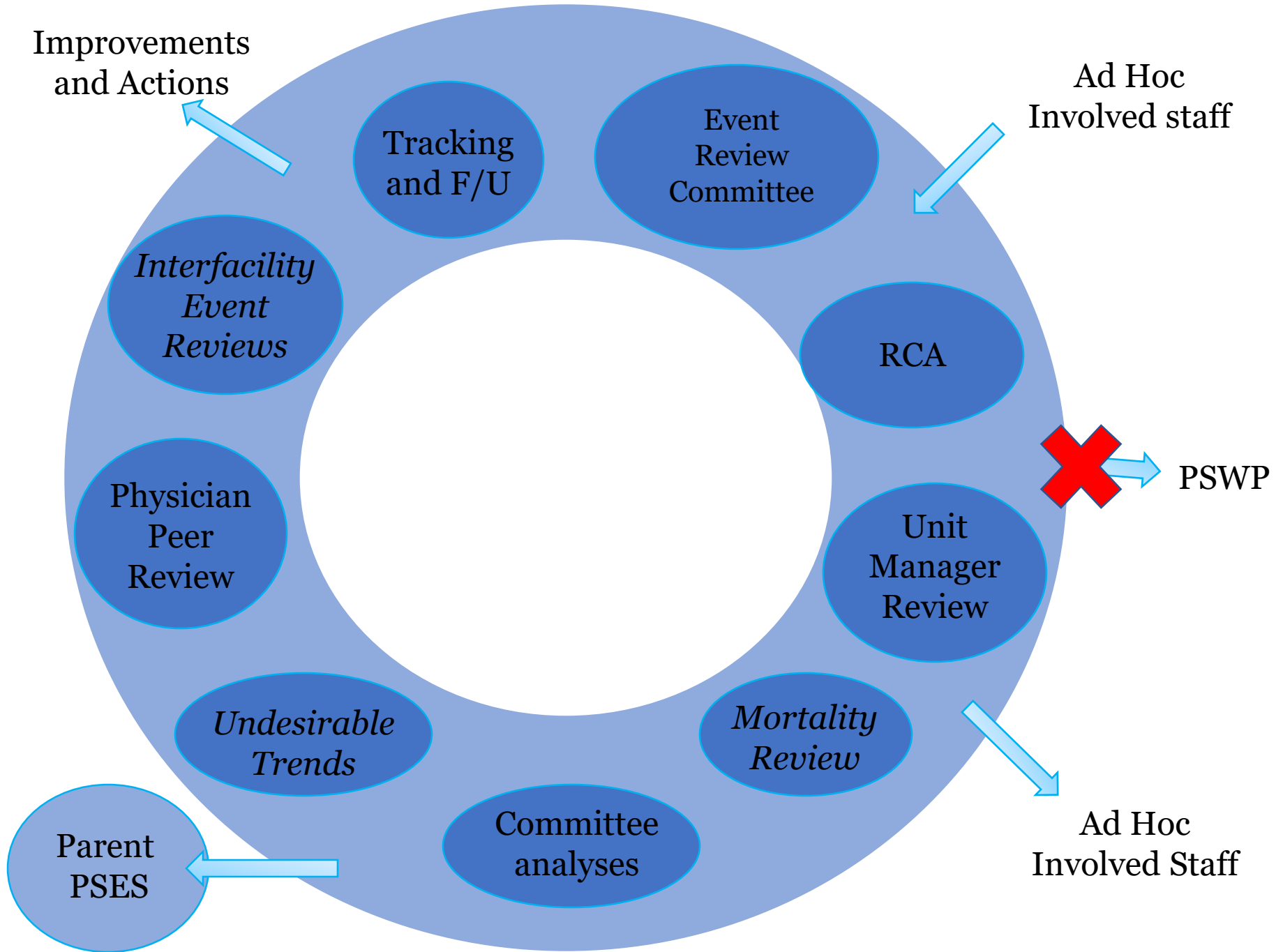
# Identified Patient Safety Activities for a Health System



# PSES Breaks the Barriers Impeding Improvement

- Many of the long-recognized impediments to successful improvement projects can be overcome, including the ***inability to protect deliberations or analyses at your facility***. The law permits providers to undertake deliberations and analyses at their facilities that become protected as Patient Safety Work Product immediately as long as they are conducted in the provider's Patient Safety Evaluation System. 73 FR 8113.
- Example: Sharing Quality Related Information between Risk, Quality, and Safety (and possibly Medical Staff) possibly at daily huddles to aligned goals, standard work for RCAs and improvement projects, and sound design principles bring everyone together with a new constancy of purpose and higher situational awareness. Create synergy between Quality, Safety, and Risk and move your organization closer to high reliability.

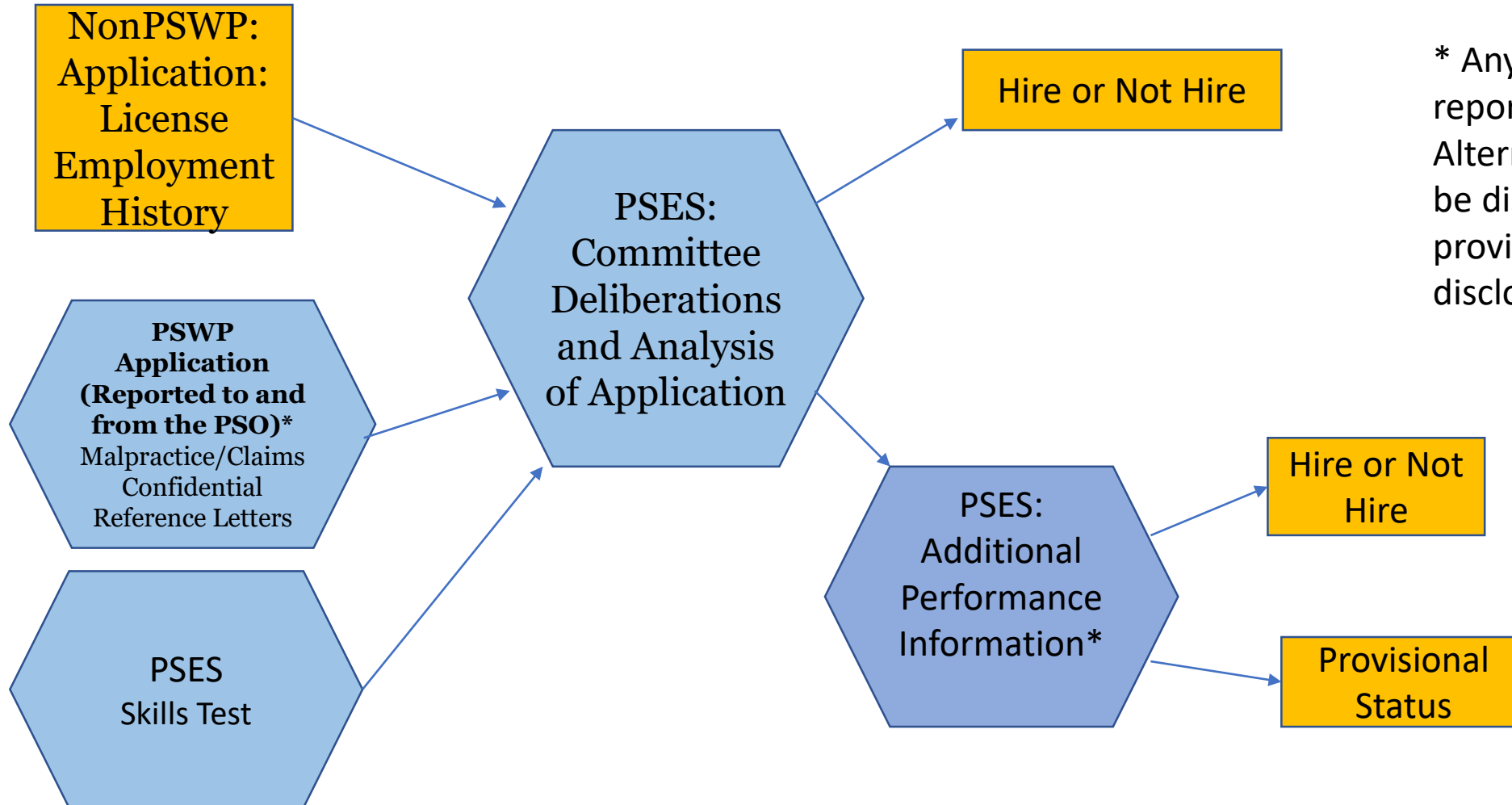
Centralized  
PSES  
For a Health  
System



# Management

- Disclosures/Use from the PSES:
  - PSWP does not lose its protections if it is removed from the PSES for internal use or external disclosure.
    - Except nonidentifiable PSWP can be voluntarily disclosed as nonprotected information.
  - Include disclosures in PSES P&P – and if all providers identified in the PSWP must agree by condition of employment/privileges – make that condition in your PSES P&P.
- Secure Storage Within or Outside of the PSES – Easier to defend if the PSWP is marked as PSWP and is maintained in a file marked as PSES.

# Use of PSWP in Credentialing



\* Any provider can report PSWP to any PSO. Alternatively, PSWP can be disclosed among providers using a disclosure permission.

# *The PSES Plan/P&P are an important roadmap --*

- Clearly delineate all of your activities within the PSES:
  - Collecting, analyzing and reporting in the “reporting” pathway.
  - Analysis and deliberations to improve patient safety/quality.
  - Receipt of feedback from the PSO to improve patient safety/quality.
  - Use within your organization (for *any* purpose).
  - Disclosure external to your organization.
- Emphasize the confidentiality and continuing privilege protections:
  - Any recipient of PSWP becomes a “responsible person” under the Act and regulations.
  - PSWP retains its privilege protection even when disclosed permissibly or impermissibly.
  - Develop consent provisions and disclosure agreements that emphasize the continuing privilege.
- Regular review and update to ensure continuing accuracy as the PSES evolves:
  - Make sure it conforms to actual practice.
  - Do not be too prescriptive or bright line.
- Make sure your defense counsel use it as a foundation for their legal arguments.

# *Rumsey v. Guthrie* (MD Pa. 2019)

- PSQIA extends privilege protection to:
  - Deliberations and analysis conducted within a PSES.
    - The proceedings and minutes of Infection Control Meetings conducted within a PSES.
  - PSO work product shared with the Provider.
    - Infection control and prevention materials received from PSO.
- PSQIA does not protect:
  - “General” infection control policies.
    - E.g., policies disseminated throughout the hospital that guide clinical decision-making.
  - Infection rate data shared with external agencies.

## *Practice Pointers:*

- The PSES can encompass the deliberations of a quality committee.
- Analysis does not need to be reported to be PSWP.
- Helpful to define what quality control activities are within the PSES and what quality control policies may be in general circulation and not PSWP.

# *Rice v. St. Louis University* (ED Mo. 2020)

- PSQIA did not extend privilege protection where:
  - Provider had a PSO contract,
  - Provider alleged that its peer review process doubled as its PSQIA investigation process, but...
  - Provider did not clearly establish how its peer review system functioned within its PSES.

## *Practice Pointers:*

- Peer review can be conducted within a PSES as deliberations and analysis within a “just culture” safety system.
- PSES should clearly document how peer review fits within the PSES.
- Helpful to define what, if any, peer review activities are conducted separately from the PSES (e.g., formal corrective action and fair hearing process).



## *Hite v. Mary Immaculate Hosp. (Va. Cir. Ct. 2020)*

- Court found PSQIA extended privilege protection to:
  - The analysis portion of an incident report, where the hospital did not claim PSWP privilege for the entire report, but only for those components that constituted analysis within the PSES.
- Court did not recognize privilege protection for:
  - Those portions of the incident report that, while claimed as PSWP by the hospital, were determined, based on *in camera* inspection, to be “more factual than deliberative.”

### Practice Pointers:

- If a provider designs its evaluation system such that (i) original incident reports are collected and maintained separately from the PSES, but (ii) subsequent analysis will be performed within the PSES, it is helpful to clearly delineate in the PSES Policy/Plan when the non-privileged incident report entered the PSES – all work product after that date is privileged PSWP.

# *Crook v. Dart* (N.D. Ill. 2019)

- PSQIA held not to extend privilege protection to:
  - Information that is “related” to information collected within a hospital’s electronic incident reporting system (eMERS), where the hospital alleges that the eMERS information “could” be reported to the PSO but does not allege that the eMERS information was generated or assembled for purpose of reporting to a PSO.

## Practice Pointers:

- Helpful to delineate how information becomes PSWP within the PSES, its management within the PSES, and its relationship to the provider’s PSO reporting system.
- If there is analysis that will not be reported then separately claim privilege under the D&A prong of the PSWP definition.

# *Ungurian v. Beyzman (Pa. Super. 2020)*

- PSQIA held not to extend privilege protection to:
  - An Event Report that was collected for reporting and reported to a PSO, where the provider did not specify that it was developed “for the purpose of reporting” to the PSO and where the Event Report was also used to improve quality at the hospital.
  - An RCA that was collected and reported to a PSO, where the provider did not specify that it was developed “for the purpose of reporting” to the PSO, and where substantive information from the RCA was disclosed to the patient’s health insurer.

## Practice Pointers:

- Helpful to clearly specify that information developed through the reporting or analysis pathways may also be used for other purposes within the organization and disclosed externally without losing its status as privileged PSWP.
- Important to claim D&A privilege in the PSES Policy and in the litigation affidavits.

# *McCue v. Integra (D. Mont. March 15, 2021)*

Hospital failed to meet its burden under the “reporting pathway” of demonstrating that its entire quality file was developed “for reporting” to its PSO.

- Court refused to apply the “deliberations and analysis” prong because the Hospital had not adequately developed that argument.
- The court said it “strained credulity” that the Hospital’s entire quality file was developed “for reporting” to its PSO.
- Court acknowledged the strong preemptive power of the PSQIA and its non-waiver provisions.

## *Practice Pointers:*

- Courts are open to the “deliberations and analysis” pathway when properly presented.
- The PSES Plan should clearly identify what “D&A” the Provider performs within its PSES.
- Defense counsel must establish the factual and legal basis of the “D&A” privilege through affidavits and briefing in opposition to Motions to Compel.

# *Tampa General v. HHS* (MD Fla 2019) vac. (11<sup>th</sup> Cir., 2/11/21)

- Hospital sought relief in the federal courts from the Florida Supreme Court's ruling in *Charles* that eviscerates PSQIA protection for event reports developed and reported to a PSO.
  - *Tampa General*: district court ruling is strongly supportive of the PSQIA privilege protection and its strong, preemptive impact on contrary state law such as Florida's Am. 7.
  - Although vacated, the opinion can still be cited for “persuasive power.”

## Practice Pointer:

- Cite *Tampa General* case for the “persuasive power” of the District Court's preemption discussion.

# *Responding to Government Inquires*

1. Educate the Surveyor.
2. Offer *non*-PSWP to satisfy the surveyor's request.
3. Obtain consent for voluntary disclosure.
4. Request Confidentiality Agreement.
5. If the PSWP must be produced without the assurance of confidentiality, create a clear record that this is PSWP and the surveyor is a "responsible person" under the law.

# Some Lessons Learned and Recommendations

- **Develop Both a Specific and Broadly Worded PSES policy**
  - One of the fundamental documents for internal educational purposes as well as to be introduced to a court in demonstrating that the materials in dispute are indeed PSWP is a provider's PSES policy.
  - The courts do not like privilege statutes and are not going to simply accept the word of the hospital or other provider that information qualifies as PSWP.
  - The provider should conduct an inventory of all its performance improvement, quality assurance, peer review, and other related patient activities as well as the various committees, reports, and other analyses being conducted within the organization.

# Some Lessons Learned and Recommendations

- This is the starting point when determining the scope of activities you wish to include within the PSES and therefore claim as privileged PSWP.
- The details of these activities and the information to be protected should be reflected within the PSES.
- When seeking to claim privilege protections over an incident report, committee minutes or other internal analysis, a provider can then cite to the specific reference within the PSES as evidence of the hospitals intent to treat this information as privileged.
- The provider should also include a “catch all” to account for other privileged patient safety activities that are not included in the PSES policy.



# Some Lessons Learned and Recommendations

- **Carefully Describe Your PSWP Pathway**

- As reflected in a number of court decisions, a provider can create PSWP via actual reporting, function reporting or through deliberations or analysis.
- It is critical that your PSES policy distinguish which forms of information, incident reports, etc., are being actually reported to the PSO or scanned and downloaded and reported and what forms of information are being treated as deliberations or analysis.
- As a practical matter, most patient safety activities can be characterized as deliberations or analysis.

# Some Lessons Learned and Recommendations

- Information that is deliberations or analysis automatically becomes PSWP when collected within the PSES and does not need to be reported to the PSO although reporting is certainly an option.
- Keep in mind too, that information which is being treated as deliberations or analysis cannot be “dropped out” but can be shared internally for any purpose and can be disclosed externally as per the applicable permissible disclosure exceptions.
- It is unlikely the hospital actually reports every single incident report to the PSO. Your PSES policy, therefore, should consider whether to treat these unreported incident reports as deliberations or analysis.

# Some Lessons Learned and Recommendations

- **Use Detailed Affidavits to Support Argument**
  - The role of the provider and its legal counsel is to effectively educate the courts about the PSA so the judges have a better understanding as to the context as to why the disputed materials are PSWP.
  - As is true in most cases, courts rely heavily on the affidavits that were submitted to demonstrate compliance with the PSA requirements in order to determine whether the information qualified as PSWP.
  - All representations in an affidavit are accepted as true unless they are otherwise rebutted.
  - Sometimes multiple affidavits maybe required.

# Some Lessons Learned and Recommendations

- **Privilege Logs**

- Some courts are requiring that the privilege logs, which identify the documents for which a state and/or the PSA privilege is asserted contain additional information such as date collected in PSES, date reported or treated as D or A, how the documents are used to improve patient care and who had access to the PSWP.
- The type of representations and documents to include within an affidavit include the following:
  - The PSO AHRQ certification and recertification letters.
  - The provider's PSO membership agreement.

# Some Lessons Learned and Recommendations

- The PSES policy.
- Citations to the policy where disputed documents are referenced and whether the information was reported to a PSO or treated as deliberations or analysis.
- Screenshots of the redacted forms, reports, etc., for which the privilege is being asserted.
- Documentation as to when the information was collected in the PSES, was reported to the PSO or when the information qualifying as deliberations or analysis was collected and/or developed within the PSES.

# Some Lessons Learned and Recommendations

- A description of how information is collected within the PSES, how it qualifies as PSWP, if not otherwise set forth in the PSES.
- Representation as to how the PSWP was or is used for internal patient safety activities to improve the quality of care and reduce risk and used by the PSO.
- Representation that the information has not been collected for unrelated purposes, such as satisfying a state or federal mandated reporting requirement but is being collected for reporting to a PSO.
- If possible, a representation that the provider is not required by state or federal law to make the information available to a government agency or other third party.

# Some Lessons Learned and Recommendations

- With respect to risk management activities, look to the nature of the activity to determine whether it is a patient safety activity which purpose is to improve patient safety and reduce risk or whether it would be considered pure claims and litigation management information.
- PSWP can and should be shared for all internal purposes where appropriate, including use in non-privileged risk management and claims activities.

# Some Lessons Learned and Recommendations

- Assert other privilege protections if applicable, state and PSA privileges are not mutually exclusive.
- Policies are not privileged.
- Update your PSES policy.
- Consider supplemental PSES policies for each affiliated entity.



# What is “Peer Review”?

- Peer review covers many categories of patient safety activities which can be included in the PSES and treated as PSWP.
- Efforts to improve patient care and reduce morbidity or mortality.
- Tracking, investigating and managing unacceptable behavior identified in Code of Conduct - Disruptive Behavior Policies.
- Physician wellness evaluations and activities.
- Evaluating healthcare providers regarding performance, skill, technique, competence, utilization, and compliance with hospital and medical staff bylaws, rules, regulations, and policies for privileging and credentialing.

# What is “Peer Review”?

- Review and establishment of standards of care.
- RCAs and analyses undertaken for the purpose of reducing the risk of harm.
- FPPE and OPPE analyses.
- Peer review monitoring, consultation requirements, collegial intervention, and similar remedial measures.
- Peer review investigations and hearings.
- All of the discussions, analyses, and work product produced by these activities.

# Questions?

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**Thank You!**